UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,182	10/05/2005	Marcia L Kalish	6395-67856-06	6209

46135 7590 02/05/2008

KLARQUIST SPARKMAN, LLP
121 S.W. SALMON STREET
SUITE 1600
PORTLAND, OR 97204

EXAMINER	
SNYDER, STUART	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,182	KALISH ET AL.	
	Examiner	Art Unit	
	Stuart W. Snyder	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 35-59* is/are pending in the application.

4a) Of the above claim(s) *1-25,35,36,39,40 and 47-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-29,36,38,41-46 and 55-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-29 and 35-59 are pending. Claims 1-25, 35, 37, 39-40, and 47-54 were previously withdrawn from consideration; claims 26-29, 36, 38, 41-46 and 55-59 as filed on 3/28/2007 are examined herein.

Specification

2. Acknowledgement is made of amendment to the Specification to correct minor typographical errors and replacement of the Sequence Listing to include SEQ ID NO: 31 in Applicants' filing of 11/15/2007. The objection to the Specification is **withdrawn**.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 26-29, 36, 38, 41-46 and 55-59 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is **withdrawn** in view of Applicants' arguments.

The Examiner suggests that to remove the ambiguity of the preamble regarding whether the claims are drawn to a process or an article of manufacturer, Applicants amend the claim to include the word "kit" or the like.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Rejection of claims 26-29, 36, 38, 41-46 and 55-59 under 35 U.S.C. 103(a) as being unpatentable over Simon, *et al.*, in view of Tam (1988), Bridon, *et al.* (1998), Silvera, *et al.* (1994), Hirsch, *et al.* (1999), and Tsujimoto, *et al.* (1988) are **maintained** for reasons of record and those below. Applicants' arguments have been carefully considered but found to be unpersuasive.

Applicant's argue that the Examiner has failed to link the cited publications to the requirement of the claims that the peptide sequences be less than 16 amino acids and recites the rationale for such a requirement from the specification; Applicants further argue that acknowledgement by Tam and Bridon, *et al.* of such a rationale is necessary for combinations of prior art to be germane to the rejection. Applicants further argue that the arts of vaccinology and diagnostics are not so closely related that one skilled in one art would not look to the other art for guidance and later, that a diagnostic artisan would not look in other virus area for guidance. Applicants argue that Bridon *et al.*'s teaching of specific HIV-1 peptides in immunoassays is fails to correct the alleged deficiencies of Simon, *et al.* because there was no recognition of the importance of the size of the peptides and no reason to combine with Tam and Simon, *et al.*

Regarding the limitation in the claim of less than 16 amino acids: The claim actually has the word "about" preceding the number 16. Clearly, 16 is not a magic number *per se* and one may reasonably construe a peptide of 20 amino acids to meet such a loose definition. There is no need for the artisans cited to recognize the rationale for the cited publications to be applicable; the need is for a skilled artisan at the time of the invention to recognize that the two or three publications teach a useful device that meets the limitations of the claims; such is the case here where Tam invented a particular version of MAPS and later (but before Applicants' filed the instant Application) recognized it's usefulness as in diagnostics. As argued below, a skilled vaccinologist would necessarily explore the diagnostic arts prior to beginning a vaccine development project. Additionally, it has long been recognized in the art of diagnostics that the shorter the peptide, the more potentially specific are the antibody-antigen reactions. Such recognition is not limited to peptide diagnostics but is more generally recognized in the field of PCR diagnostics; primers and probes are designed to possess sufficient affinity for the target regions while at the same time be sufficiently specific for the target but not unrelated polynucleotides. Applicants' argument that there is little cross-fertilization between diagnostics and vaccinology arts is not convincing; the Examiner has previously worked and published in both arts. From this personal experience, the Examiner knows that one does not embark on a vaccine development program without acquiring diagnostic capabilities necessary to evaluate vaccine candidates. Furthermore, the literature, patent and non-patent,

is replete with skilled vaccine development artisans describing readily available and "in-house" diagnostic tools--two examples of such can be seen in the cited publications.

Finally, with regard to Applicants' arguments concerning non-obviousness to combine, the Examiner, while relying solely on the above cited art to teach obviousness, notes that others in the arts and prior to Applicants' filing were practicing similar diagnostic methods as those claimed in the instant Application. One investigative team suggested in one publication (Jackwood and Hilt, 1995) that constructs similar to Tam's would be useful in diagnostics, specifically ELISA and dot blot assays (see abstract and discussion sections) whilst Tam's group published just such an ELISA method (see Tam and Zavala). Tam and Zavala teach a radioimmunoassay method and reagents for use of the method including the use of peptides of 12 and 17 amino acids each of which meet the limitation of "less than about 16 amino acid residues". Tam and Zavala specifically teach that the use of the MAP increased the avidity of the antibodies for the peptides (see especially, the results section entitled "comparison of MAP with monomer as coating antigen). Thus, the art cited in the obviousness rejections of the previous Office Action fully supports the Examiner's obviousness-to-combine reasoning. The Examiner acknowledges the typographical error regarding Bridon, *et al.* and inadvertent replacement of HIV by SIV. The factual basis for combining Bridon, *et al.* and Tam is explained above and in the previous Office action but correctly referring to HIV.

4. Rejection of claims 36, 41-43, 46, 56, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon, *et al.* (2001), Tam (1988), and Bridon, *et al.* (1998) as applied to claims 26-29, 38, 44, 55, 57, and 59 above, and further in view of Silvera, *et al.*, Hirsch, *et al.*, and Tsujimoto, *et al.* is **maintained**. Applicants' arguments have been carefully considered and have not been found to be persuasive. Applicants' rebuttal of the instant rejection is that the underlying deficiency of Simon, *et al.*, Tam, and Bridon, *et al.* is not corrected by Silvera, *et al.*, Hirsch, *et al.*, and Tsujimoto, *et al.* However, as demonstrated above, there is no underlying deficiency and Applicants' arguments are moot.

Conclusion

5. No claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stuart W Snyder
Examiner
Art Unit 1648

SWS

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER